UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,122	08/10/2001	Daniel P. Gold	032077.0002.UTL	4261

21971 7590 07/07/2006

WILSON SONSINI GOODRICH & ROSATI
650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,122	GOLD ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *18,19,22 and 38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,20,21,23-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election of group I in the reply filed on 8/26/2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 39-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/30/2003.

3. Applicant's election with traverse of the species noted in the reply filed on 8/26/2003 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding applicants comments, the species (a) and (c) referred to in the Office Action of 4/22/03 are chemically and functionally distinct and have different amino acid sequences. The diseases of species (B) are distinct because they have different pathologies and symptoms.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 22,38,18,19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/30/2003. Regarding claims 18,19, said claims are drawn to a chimeric protein that contains a carrier not found in the elected species as per the response filed 10/30/2003.

5. Claims 1-17,20,21,23-37 are under consideration.

6. Applicant needs to amend the first paragraph of specification to list filing dates of the cited US provisional applications.

7. The abstract of the disclosure is objected to because the abstract must be less than 150 words (see 37 CFR 1.72(b). Correction is required. See MPEP § 608.01(b).

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1,2,4-17,23-27,29-31,33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Weidanz et al. (WO 99/18129).

Weidanz et al. disclose a TCR Vbeta/Cbeta attached by a linker to a Valpha/Calpha wherein said construct is linked to human Ig C kappa constant regions (see claims 1-22 and page 17). Weidanz et al. disclose use of various lengths of Calpha or C beta wherein the C region is less than the native C region molecule (see claims 7-8). Said C regions comprise the first nine amino acids of the TCR C region. Weidanz et al. disclose an in vivo method of treatment with said construct to treat disease mediated by pathogenic T cells (see claim 39, page 11). The TCR chains used in the chimeric protein are derived from pathogenic T cells in the patient (see page 11 and 22-26). Weidanz et al. disclose that the chimeric protein can be made in insect cells using baculovirus. The recitation of a particular means wherein the baculovirus produced chimeric protein is made carries no patentable weight. Weidanz et al. teach polyvalent multimers of the aforementioned chimeric TCR wherein said molecules would have multiple constant region chains (see page 35, last paragraph).

10. Claims 1,2,4-8,10-13,15-17,23-27,31,33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by McKeever et al.

McKeever et al. disclose administration of a chimeric TCR/IgG1 TCR construct to alter a T cell mediated pathology in a patient (mouse, wherein a mouse is a patient as per defined in the specification)(see Summary and pages 1764-66). The baculovirus produced chimeric TCR construct used is described in Figure 1 and Methods and Materials section. The construct contains a TCR Valpha/Calpha attached via a linker to a IgG1 heavy and a TCR Vbeta/Cbeta attached via a linker to a IgG1 heavy chain (see Figure 1 and Methods and Materials section). The recitation of a particular means

wherein the baculovirus produced chimeric protein is made carries no patentable weight. The TCRs are derived from T cells which cause a pathology in the patient (see summary).

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1,2,4-17,23-27,29-31,33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weidanz et al. (WO 99/18129) in view of Brostoff et al. (WO 94/25063).

Weidanz et al. disclose a TCR Vbeta/Cbeta attached by a linker to a Valpha/Calpha wherein said construct is linked to human Ig C kappa constant regions (see claims 1-22 and page 17). Weidanz et al. disclose use of various lengths of Calpha or C beta wherein the C region is less than the native C region molecule (see claims 7-8). Said C regions comprise the first nine amino acids of the TCR C region. Weidanz et al. disclose an in vivo method of treatment with said construct to treat disease mediated by pathogenic T cells (see claim 39, page 11). The TCR chains used in the chimeric protein are derived from pathogenic T cells in the patient (see page 11 and 22-26). Weidanz et al. disclose that the chimeric protein can be made in insect cells using baculovirus. The recitation of a particular means wherein the baculovirus produced chimeric protein is made carries no patentable weight. Weidanz et al. teach polyvalent multimers of the aforementioned chimeric TCR wherein said molecules would have multiple constant region chains (see page 35, last paragraph). Weidanz et al. do not teach that said method can be used to treat T cell lymphoma. Brostoff et al. teach treatment of T cell lymphoma by administration of TCR derived from a T cell lymphoma (see page 2, last paragraph, continued on next page and page 3, last paragraph, continued on next page). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention

because Weidanz et al. disclose an in vivo method of treatment with chimeric T cell receptors to treat disease mediated by pathogenic T cells which express said receptor and Brostoff et al. teach treatment of T cell lymphoma (a T cell mediate pathology) by administration of TCR derived from a T cell lymphoma (see page 2, last paragraph, continued on next page and page 3, last paragraph, continued on next page). One of ordinary skill in the art would have been motivated to do the aformentioned because Brostoff et al. teach treatment of T cell lymphoma (a T cell mediate pathology) by administration of TCR derived from a T cell lymphoma.

13. Claims 1-17,23-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weidanz et al. (WO 99/18129) in view of Lebowitz et al..

Weidanz et al. disclose a TCR Vbeta/Cbeta attached by a linker to a Valpha/Calpha wherein said construct is linked to human Ig C kappa constant regions (see claims 1-22 and page 17). Weidanz et al. disclose use of various lengths of Calpha or C beta wherein the C region is less than the native C region molecule (see claims 7-8). Said C regions comprise the first nine amino acids of the TCR C region. Weidanz et al. disclose an in vivo method of treatment with said construct to treat disease mediated by pathogenic T cells (see claim 39, page 11). The TCR chains used in the chimeric protein are derived from pathogenic T cells in the patient (see page 11 and 22-26). Weidanz et al. disclose that the chimeric protein can be made in insect cells using baculovirus. The recitation of a particular means wherein the baculovirus produced chimeric protein is made carries no patentable weight. Weidanz et al. teach polyvalent multimers of the aforementioned chimeric TCR wherein said molecules would have multiple constant region chains (see page 35, last paragraph). Weidanz et al. do not teach that said method using the chimeric protein of claim 32. Lebowitz et al. teach soluble high affinity chimeric TCR protein of claim 32 (see Figure 1 and 2). A routineer would have prepared said protein using human constant regions for use in humans as per disclosed by Lebowitz et al. (see abstract). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Weidanz et al. disclose an in vivo method of treatment with chimeric T cell receptors to treat disease mediated by pathogenic T cells which express said receptor and Lebowitz et al. teach soluble high affinity chimeric TCR protein of claim 32 (see Figure 1 and 2). One of ordinary skill in the art would have been

motivated to do the aformentioned because Lebowitz et al. teach that their chimeric TCR protein is soluble and of high affinity and can be used in vivo to treat disease (see abstract)

14. Claims 1,2,4-17,20,21,23-27,29-31,33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weidanz et al. (WO 99/18129) in view of Bonnem et al. (WO 94/01133).

Weidanz et al. disclose a TCR Vbeta/Cbeta attached by a linker to a Valpha/Calpha wherein said construct is linked to human Ig C kappa constant regions (see claims 1-22 and page 17). Weidanz et al. disclose use of various lengths of Calpha or C beta wherein the C region is less than the native C region molecule (see claims 7-8). Said C regions comprise the first nine amino acids of the TCR C region. Weidanz et al. disclose an in vivo method of treatment with said construct to treat disease mediated by pathogenic T cells (see claim 39, page 11). The TCR chains used in the chimeric protein are derived from pathogenic T cells in the patient (see page 11 and 22-26). Weidanz et al. disclose that the chimeric protein can be made in insect cells using baculovirus. The recitation of a particular means wherein the baculovirus produced chimeric protein is made carries no patentable weight. Weidanz et al. teach polyvalent multimers of the aforementioned chimeric TCR wherein said molecules would have multiple constant region chains (see page 35, last paragraph). Weidanz et al. do not teach that said method can be used with GM-CSF. Bonnem et al. disclose that GM-CSF can be administered to increase the immune response to an administered antigen (see claim 1 and abstract). Weidanz et al. disclose that their method can act by immunizing humans against pathogenic T cells which express the target TCR (see page 6, last paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Weidanz et al. disclose that their method can act by immunizing humans against pathogenic T cells which express the target TCR whilst Bonnem et al. disclose that GM-CSF can be administered to increase the immune response to an administered antigen. On of ordinary skill in the art would have been motivated to do the aformentioned because Bonnem et al. disclose that GM-CSF can be administered to increase the immune response to an administered antigen.

15. No claim is allowed.

15. References not considered on the supplied IDSs were not considered because they were foreign language documents not in compliance with the requirements under MPEP 609, documents with incomplete citations, abstracts with no citation information or incomplete documents.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644